

### REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above claim amendments and remarks that follow. Claims 27-37, 41, and 43-51 are pending.

#### Rejections under 35 U.S.C. §112

Claims 27-37, 41, 43-45, 47, 49, and 51 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicant respectfully traverses this rejection.

Claims 43-45 (and dependant claims 27-37, 41, 47, 49, and 51) are rejected for use of the term “recombinant.” The examiner argues the term is indefinite because the specification discloses a definition that allegedly makes the claims unclear.

The examiner argues that MPEP 2106 controls because the examiner appears to interpret paragraph [0070] of the present application as defining the term recombinant in a manner that is inconsistent with the art recognized definition. This is in improper characterization of the present application. In paragraph [0070], the Applicant merely provides examples of what may be considered to be encompassed by the word “recombinant” and has not tried to re-define the term as alleged by the examiner.

The examiner alludes to MPEP 2111, but the examiner does not appear to deem it necessary to actually apply the tenets of law set forth therein. MPEP 2111.01 expressly states that although claims of issued patents are interpreted in light of the specification, prosecution history, prior art, and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004). Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. As pointed out by the Federal Circuit in *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003), “Interpretation of descriptive statements in a patent's written description is a

difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims ‘in view of the specification’ without unnecessarily importing limitations from the specification into the claims.” As pointed out by the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) (*en banc*), “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application.” It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the “ordinary” and the “customary” meaning of the terms in the claims. As the Federal Circuit point out in the case of *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994), an applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning.

The examiner has not applied the proper approach to the claim terms. The examiner has not given the claim terms their broadest possible meaning. The examiner has ignored the fact that the term “recombinant” is used in the present claims in a manner consistent with the ordinary and customary meaning. The examiner has not argued that the disclosure of paragraph [0070] provides a different definition than the ordinary and customary meaning. The examiner only argues that the examiner does not understand the scope of the disclosure in paragraph [0070]. That is not the proper basis for such a rejection. Applicant submits that the claim term “recombinant” is presently recited in the context of its ordinary and customary meaning, and the present specification has not expressly re-defined the term in any inconsistent manner.

Further to the above, Applicant notes on page 30 of the present office action that the examiner argues that “***the structure of insulin is the same regardless of whether it is isolated or synthesized.***” Applicant submits it is improper for the examiner to argue on one hand that the presently recited recombinant insulin is indefinite and on the other hand argue that the method of preparation of the insulin has no effect on the structure. If, as the examiner argues, the structure is the same regardless of the method of making the insulin, it is de facto the case

that one of ordinary skill in the art would have a clear understanding of the presently claimed recombinant insulin regardless of the examiner's arguments related to the present specification. The examiner has made opposing arguments around the same claim language to support two different rejections, and both positions cannot simultaneously exist. Applicant submits that this is a further example showing that one of skill in the art would clearly understand what is meant in the present claims by the word "recombinant".

In light of the above comments, Applicant submits that the present rejection is improperly applied. Thus, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. §102

Claims 27-29, 35, 41, 43-45, 47, 49, and 51 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schröder (Methods in Enzymology, 1985). Applicant respectfully traverses this rejection.

Regarding claims 41, 43, and 45, the examiner admits that these claims recite properties that are not reported by Schröder; however, the examiner attempts to shift the burden to the Applicant to prove that the Schröder compositions would not exhibit the recited properties. This is improper. The examiner blindly includes boilerplate language citing to *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). The examiner has failed to follow the proper course in reaching this argument. MPEP 2112(V) states that once a reference teaching a product appearing to be substantially identical to is made the basis of a rejection, **and** the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference. The examiner has in no way shown that the Schröder product would inherently include the presently recited properties. To this end, the examiner is reminded that to establish inherency, the extrinsic evidence that is relied upon must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing **may** result

from a given set of circumstances is not sufficient. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). See also MPEP 2112.

In specific relation to present claim 43, the examiner again improperly imports definitions from the specification into the claims in order to make arguments that the Schröder composition exhibits the same properties. In this case, the examiner actually makes his own definition of what a “shell” would be when the word “shell” is not even included in the claims. For example, the examiner argues that the Schröder composition cannot act as shells because the entrapped substance is released. This is an untenable argument. The examiner has not provided any evidence even to support the examiner’s own incorrect definition of the word shell. The word shell can mean “something resembling or having the form of a shell.” Moreover, as Applicant has previously pointed out, there **is** an escape from a shell – the shell is merely broken (e.g., degraded or dissolved).

Thus, the examiner is improperly importing the examiner’s own definition to define a word that is not even present in the claims so as to ignore Applicant’s correct evaluation of Schröder as lacking any disclosure of the presently claimed composition wherein “none of the insulin is encapsulated.” To this end, Applicant again points out that at page 120 (under the heading “Crystallized Carbohydrate Spheres (CCS) for Slow Release”), Schröder discloses that his composition relates totally to **entrapment** of substances for slow release. The text thereafter discloses that the dextran and the active substance “to be entrapped” are co-dissolved and then precipitated to form spheres wherein the active substance is entrapped therein. Thus, it is clear that the Schröder composition relies exactly upon the type of entrapment or encapsulation that the presently claimed invention distinguishes and overcomes.

In the present office action, the examiner points to Lengsfeld to argue that entrapment and encapsulation are not equivalents. First, this is of no relevance because, whether either word is used, the presently claimed composition still is not disclosed by Schröder. Second, the examiner’s mincing of words is of no effect because, by either definition, the drug component is surrounded by or within the polymer matrix or shell. This is what Schröder teaches – i.e., insulin within or completely surrounded by the polymer. The present claims

differ because the insulin is within pores and this is not within or completely surrounded by the polymer (i.e., the pores remain open to the environment for release of the drug). Third, Lengsfeld was only accessed by the examiner on October 15, 2010. The examiner has pointed to nothing confirming that this art was available at the time of filing of the present application.

The examiner also continues to argue that Schröder discloses pores in the polymer matrix at page 117. Therein, however, Schröder teaches entrapment of proteins in a nonbiodegradable polymer matrix, and examiner's reliance upon this disclosure is improper. This is a disclosure of the *prior art* from which Schröder *teaches away*. The actual Schröder composition is not formed of a nonbiodegradable polymer matrix. Moreover, Schröder does not teach that its composition of dextran and insulin is porous. Still further, Schröder in no way suggests that the prior art composition could be combined with actual Schröder compositions. Since the present claims exclude entrapment and expressly require porosity, the disclosure at page 117 of Schröder is of no effect on the present claims.

The examiner continues to allege that Schröder discloses in Figure 1 that the crystalline polymer matrix has pores. A prior art document must be relied upon for what it teaches, not for the examiner's interpretation of a figure therein. The examiner has pointed to no portion of Schröder in relation to Figure 1 that teaches that the figure illustrates pores in its dextran microspheres. In the caption, FIG. 1 (a) and FIG. 1(b) are described as being schematic views. A skilled person would recognize that a "schematic" is a representation of the elements of a system using abstract, graphic symbols rather than realistic pictures. A schematic usually omits all details that are not relevant to the information the schematic is intended to convey, and may add unrealistic elements that aid comprehension. Nothing in Schröder teaches that the matter schematically illustrated in Figure 1 is a realistic drawing showing pores in the dextran microspheres. Unless the examiner can point to specific text in Schröder expressly teaching the presence of pores, it is improper and against prevailing law for the examiner to make an unsupported interpretation of a schematic drawing. The examiner cannot lawfully form a completely unsupported opinion as to what a schematic illustrates and then shift the burden to the Applicant to prove otherwise. This is an improper

examination tactic. Moreover, the examiner's opinion as to what is schematically illustrated in Figure 1 of Schröder is clear evidence of improper hindsight unless the examiner can point to some teaching in Schröder to support the opinion.

In response, the examiner improperly relies upon MPEP 2113 to sidestep the issue. The examiner argues that the present claims are product by process claims. That is an improper characterization that is self-servingly promulgated by the examiner so the examiner can thereafter argue that the Office bears a lesser burden of proof in making out a case of *prima facie* obviousness. This is totally improper because the present claims in no way claim a product in terms of a process. Rather, the claims recite specific properties of the product (e.g., "none of the insulin is encapsulated", and "the insulin is in the pores of the microparticles"). These phrases describe the nature of the end product and do not claim the product in terms of process steps. Moreover, the present rejection is an **anticipation** rejection, not an **obviousness** rejection. The burden of the Office is clear – the examiner must show that each and every aspect of the claims is expressly or inherently present in the cited art. The examiner has not done this and has resorted to incorrect application of the law to avoid making a proper rejection.

In light of the above comments, Applicant submits that the examiner has not set forth a proper basis to show that the presently claimed compositions are anticipated by Schröder. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

#### Rejections under 35 U.S.C. §103

Claims 27-29, 32-33, 35, 37, 41, and 43-51 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) and Moriyama (Journal of Controlled Release, 1996). Claims 27-29, 32-33, 35, 37, 41, and 43-51 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) and Moriyama (Journal of Controlled Release), and Medline (Medline entry from STN for "Crystallized carbohydrate spheres for slow release and targeting", entered Medline Nov. 1, 1985), and Registry (Registry entry for 11061-68-0, entered Nov. 16, 1984). Claims 27-29,

31, 35-37, 41, and 43-51 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) and Ecanow (U.S. Patent No. 4,963,526). Claims 27-29, 31, 35-37, 41, and 43-51 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) and Ecanow (U.S. Patent No. 4,963,526) and Medline (Medline entry from STN for “Crystallized carbohydrate spheres for slow release and targeting”, entered Medline Nov. 1, 2985), and Registry (Registry entry for 11061-68-0, entered Nov. 16, 1984). Claims 27-30, 34, 35, 41, and 43-51 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) and Clark et al. (U.S. Patent No. 5,783,556). Claims 27-30, 34, 35, 41, and 43-51 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) and Clark et al. (U.S. Patent No. 5,783,556), and Medline (Medline entry from STN for “Crystallized carbohydrate spheres for slow release and targeting”, entered Medline Nov. 1, 2985), and Registry (Registry entry for 11061-68-0, entered Nov. 16, 1984). Applicant respectfully traverses these rejections.

Schröder does **not** disclose a composition exhibiting the following characteristics: 1) none of the insulin is encapsulated; 2) the insulin is located in pores of the crystallized dextran microparticles; 3) the crystallized dextran microparticles are porous and particularly have a porosity of at least 10% by volume. Since none of the secondary cited references cures this deficiency of Schröder, Applicant submits the present rejections have been improperly applied. Thus, Applicant requests reconsideration and withdrawal of the rejections.

### Conclusion

Applicant respectfully submits that all claims, as now submitted, are in condition for immediate allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor formalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration

of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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